Arcos

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Burn Resuscitation Decision Support System
510(k) Summary

APR 1 8 2013

Submitted by:	Arcos, Inc. 866 W. 41st St. Houston, TX 77018
Contact:	Chris Meador 713-397-3030
Date Prepared:	May 25, 2012
Product Trade Name:	Burn Resuscitation Decision Support System (BRDSS)
Common Name:	Drug Calculator
Classification:	Class II
Classification Name:	21 CFR 868.1890, *Predictive Pulmonary-function value calculator.* Product Code: PDT
Predicate Device:	K011571, TRxF Intelligent Dosing System™
Device Description:	The BRDSS is a fluid calculator for use in the care of seriously burned patients. It is used to calculate the next dose of fluid for patients.

Indications For Use

The Burn Resuscitation Decision Support System (BRDSS) is indicated for use in the care of adult patients with 20% or more Total Body Surface Area (TBSA) burned as a fluid resuscitation calculator for hourly fluid recommendations. The BRDSS is intended to be initiated within 24 hours of the burn.

Substantial Equivalence

A. Predicate Device Comparison

	Predicate Device K011571 TRxF Intelligent Dosing System™	**Applicant Burn Resuscitation Decision Support System (BRDSS)**
Device Description	The IDS™ is a next-dose calculator for any drug that can be used by physicians to calculate the next dose for patients.	The BRDSS is a fluid calculator for use in the care of seriously burned patients. It is used to calculate the next dose of fluid for patients.

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Intended Use	The IDS is a software-based drug-dosing calculator designed for use by the physician to calculate the next dose of any drug to achieve a desired target.	The Burn Resuscitation Decision Support System (BRDSS) is indicated for use in the care of adult patients with 20% or more Total Body Surface Area (TBSA) burned, as a fluid resuscitation calculator for hourly fluid recommendations. The BRDSS is intended to be initiated within 24 hours of the burn incident and ending by 72 hours post burn.
Intended User	Healthcare professional	Healthcare professional
Intended Use Environment	Health care facility	Hospital critical-care environment
Human Factors	Physician enters patient's glucose values and amounts of insulin. Warnings are presented when values are out of range and /or insulin doses are greater than or less than 20% of the most recent dose.	Physician or nurse enters patient weight, % of body surface area burned and time of burn. Warnings are presented when the primary fluid rate recommendation is +/- 25% (and +/- 200mL/hr) from the current primary fluid rate dose. In addition, graphs are included to show patient's cumulative volume of fluids received and hourly fluids in and urine out.
Software-Based	Yes	Yes
Dose Calculation	Yes	Yes

B. Non-Clinical Data

The BRDSS adheres to hardware requirements, such as form factor and power requirements, as well as software requirements, such as data input validation, user warnings, alerts and messages, user interface requirements, functional requirements and error handling requirements. The BRDSS includes many human factors best practices for the software user interface.

The BRDSS has passed product verification as well as clinical user validation.

Substantial Equivalence

The BRDSS and the predicate device, the TRxF Intelligent Dosing System, are both portable software-based systems that allow the healthcare professional to calculate dosages of either medicines or fluids to a patient. Both devices provide dose calculations based on relevant patient clinical data. The indications for use are very similar, and the technological and human factors features are essentially identical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

April 18, 2013

Arcos, Incorporated
% Mr. Chris Meador
866 West 41st Street
Houston, Texas 77018

Re: K121659
Trade/Device Name: Burn Resuscitation Decision Support Software (BRDSS)
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive pulmonary-function value calculator
Regulatory Class: Class II
Product Code: PDT
Dated: February 28, 2013
Received: March 04, 2013

Dear Mr. Meador:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours, FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121659

Device Name: Burn Resuscitation Decision Support System (BRDSS)

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Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K121659